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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Anatoly Giritch

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EXAMINER

BUI, PHUONG T

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/544,135	Applicant(s) GIRITCH ET AL.	
	Examiner Phuong T. Bui	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 28-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :7/29/05,10/20/08,11/24/08,3/18/10.

DETAILED ACTION

1. The Office acknowledges the receipt of Applicant's restriction election filed July 14, 2010. Applicant elects Group I claim 1-27 without traverse. Claims 1-33 are pending. Claims 28-33 are withdrawn from examination. Claims 1-27 are examined in the instant application. This restriction is made FINAL.

Applicant's earliest priority benefit is January 31, 2003.

Claim Objections

2. Claim 16 is objected to because of the following: the claim ends with a comma. Correction is required.

Information Disclosure Statement

3. Signed copies of Applicant's IDS filed July 29, 2005, October 20, 2008, November 24, 2008 and March 18, 2010 are attached to the instant Office action.

Claim Rejections - 35 USC § 112, second paragraph

4. Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, transgenic plants or plants cells cannot be stably transformed on a chromosome.

In claim 1(a), it is suggested "plant cells or plants" be amended to "a plant cell". Otherwise, the claim reads on one vector per plant or plant cell, which does not appear to be Applicant's intention or supported by the specification.

In claim 1, a function cannot be expressed. Does Applicant mean a polypeptide?

In claim 1, it is unclear what “capable” refers to: plants/cells, chromosome or DNA sequence of interest.

In claim 1(iii), “from at least two of said at least two different vectors” is unclear. It is suggested “at least two of” be deleted.

In claim 18, it is unclear what is being screened for. It is unclear what the recombination products encompass. See also claim 19.

In claim 21, it is unclear how the DNA sequence of interest can comprise intron-mediated cis-splicing, as splicing is a step and not a product.

In claim 24, it is unclear whether the DNA sequence of interest contains a sequence portion of the two vectors, or the two vectors contain a sequence portion of the DNA sequence of interest.

In claim 25, it is unclear whether what is in the parenthesis is intended to be a claim limitation. Moreover, the Markush grouping to be selected from cannot be an open set. See also claim 26.

In claim 26, it is unclear how a_1b_1 differs from b_1a_1 .

In claim 27, it is unclear what function the primary, secondary and their combination portions have. The function is not disclosed.

Clarification and/correction is required.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent

and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 21 and 22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 9-12, 14, 17 and 20-22 of copending Application No. 10/544135. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed

methods in both applications are directed to introducing a sequence of interest into a plant genome using two vectors and intron-mediated cis-splicing to excise the intron, resulting in a functional sequence of interest. The DNA of interest is obvious in view of the RNA of interest because DNA is converted to RNA before it is expressed. Each vector of the instant application would inherently possess a transcriptional promoter and translation regulatory element to express the sequence of interest.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Klimyuk et al. (US20050066384 (A)).

Klimyuk teaches a method of producing a transgenic plant cell containing and expressing a stably transformed DNA sequence of interest into the plant nuclear chromosome by site-specific homologous recombination, whereby the cell has been transformed with at least two different vectors that are adapted to recombine with each

other by site specific recombination resulting in a non-replicating recombination product containing the DNA sequence of interest, and whereby the DNA sequence of interest contains sequence portions from the at least two different vectors necessary to express the DNA sequence of interest ([0037], [0052], [0077], [0137], claim 25). Klimyuk also teaches selecting for cells expressing the DNA sequence of interest (claims 1 and 26), screening for plant cells in which site specific recombination between the two vectors has occurred (Abstract), screening for plant cells containing the DNA sequence of interest integrated in the chromosome (claim 2), screening for the expressed DNA sequence of interest [0058], *Agrobacterium*-mediated delivery (claim 5) or direct nucleic acid transfer [0087], delivery of each vector by different *Agrobacterium* cells [0053], recombinase [0053], destroyed recombinase coding sequence (claim 28), intron-mediated cis-splicing [0124], the vector components of claim 22 (see claims 26 and 33) and T-DNA border sequences for integration (Figs, 11, 12 and 14). The *Agrobacterium* plasmids used by Klimyuk would inherently contain cytokinin autonomy gene. Klimyuk further teaches a selectable marker gene and IRES element, whereby the selectable marker is not transcribed in the plant cell and allows for screening for the absence of the recombination products [0198]. Plant cells containing different DNA sequences of interest are produced in the methods of Klimyuk. Vectors, including a vector containing the recombinase coding sequence and vectors containing different sequence portions which recombine to express a DNA sequence of interest, are also taught (claim 25). Accordingly, Klimyuk anticipates the claimed invention.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

9. Claims 1-3, 5, 9-15, 18, 19 and 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Offringa et al. (US5501967 (B)). Offringa teaches a site-specific homologous recombination method for producing transgenic plants stably transformed on a chromosome with two vectors introduced by two different *Agrobacterium* strains, each vector containing a defective NPTII gene, whereby homologous recombination in a plant cell between two T-DNAs of the two vectors results in kanamycin resistant plant cells (Abstract, col. 6, Ins. 10-27). Offringa also teaches direct nucleic acid transfer (col. 8, Ins. 13-14) and various screening and selection methods, both positive and negative (cols. 7 and 8). Accordingly, Offringa anticipates the claimed invention.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-15, 18, 19 and 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Offringa et al. (US5501967 (B)), as applied to claims 1-3, 5, 9-15, 18, 19 and 24-27 above, and further in view of Fabijanski et al. (US7112721 (C)).

The teachings of Offringa have been discussed supra. Offringa does not teach a functional cytokinin autonomy gene, a site-specific recombinase or an intron.

Fabijanski teaches a method for introducing a DNA sequence of interest into the plant genome by introducing a vector containing a DNA sequence of interest and an *Agrobacterium* oncogene (same as Applicant's cytokinin autonomy gene, see col. 24, lns. 50-51) to select for transformed cells, whereby the oncogene region is later excised by site-specific recombinase and the DNA sequence of interest is inserted into the plant genome by homologous recombination (see Figs. 2-8). Fabijanski also teaches the inclusion of a plant intron to prevent expression in bacteria cells (col. 20, lns. 23-34).

It would have been *prima facie* obvious to one skilled in the art at the time the invention was made to include the oncogene and recombinase coding sequence of Fabijanski in one of the vectors of Offringa for the purpose of increasing the efficiency of the screening/selecting for transformants. Selecting for transformants has been recognized in the art as being problematic (see Background of the Invention of Fabijanski). The method of Fabijanski would allow one skilled in the art to efficiently screen for transformants and producing a marker-free plant cell containing only the DNA of interest, whereby the sequence coding for recombinase is destroyed by site-specific recombination (Fig. 8). The inclusion of a partial intron linked to the defective NPTII gene on each of the two vectors of Offringa resulting in the inserting into the plant

genome two NPTII gene sequences flanking a plant intron is also obvious to prevent expression of NPTII in bacterial cells. The plant intron is removed by plant machinery via intron-mediated cis-splicing. The inclusion of a third vector containing a recombinase coding sequence to excise other selection markers such as antibiotic resistance is a matter of design choice without any surprising or unexpected results (see Fig. 5). Accordingly, one skilled in the art would have been motivated to produce the claimed invention with a reasonable expectation of success.

12. Claims 1-3, 5, 9-20 and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Offringa et al. (US5501967 (B)), as applied to claims 1-3, 5, 9-15, 18, 19 and 24-27 above, and further in view of Atabekov et al. (US6376745 (D)).

The teachings of Offringa have been discussed supra. Offringa further teaches a negative selection gene (Abstract, same as Applicant's counter-selectable marker gene). Offringa does not teach an IRES element.

Atabekov teaches gene expression under the control of IRES (Abstract). Advantages for using IRES for gene expression are also taught (col. 4, Ins. 16-67).

It would have been *prima facie* obvious to one skilled in the art at the time the invention was made to modify one of the two vectors of Offringa to include an IRES element for expression of a selectable marker for the purpose of selecting for plant transformants. The advantages of including an IRES element are taught by Atabekov. It would also have been obvious to allow transcription of the selectable marker as a result of site-specific recombination rather than from one of the vectors of Offringa to select for transformants that have undergone site-specific recombination in the

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homologous recombination method of Offringa. The use of a positive or negative selectable marker is a matter of design choice without any surprising or unexpected results. Accordingly, one skilled in the art would have been motivated to produce the claimed invention with a reasonable expectation of success.

Remarks

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong T. Bui whose telephone number is 571-272-0793.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phuong T. Bui/
Primary Examiner, Art Unit 1638